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Jeil Medical Corporation

Exhibit 5 510(k) Summary of Safety and Effectiveness

NOV 18 2009

Model: LeForte Neuro System Bone Screw (Various Models)

1. Submitter and US Official Correspondent

Submitter:	Jeil Medical Corporation
Address:	#702, Kolon Science Valley 2nd
	811, Guro-dong, Guro-gu
	Seoul, 152-050, Korea
Official Correspondent:	Shin Kuk Yoo, Consultant
Telephone No.:	714-313-7442
Fax No.:	801-303-7455
Email:	skyone@LSKBioPartners.com

2. Establishment Registration Number

3004049923

3. Device Information

Proprietary/Trade Name:	LeForte Neuro System Bone Screw
Common/Usual Name:	Bone Screw
Classification Name:	Screw, Fixation, Intraosseous
Classification Product Code:	DZL
Device Class:	Class II per regulation 21 CFR 872.4880

4. New or Modification

The application is intended for premarket notification of new medical device, LeForte Neuro System Bone Screw, for US market

5. Predicate Legally Marketed Device

1) Plate, Bone (**Model: Synthes (USA) Neuro Plate and Screw System**) manufactured by Synthes (USA) – K042365, Decision Date: 11/18/2004, JEY (Class II per regulation 21CRF 872.4760)

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2) Screw, Fixation, Intraosseous (**Model: Synthes (USA) 1.3mm Craniofacial Screws**) manufactured by Synthes (USA) – K021850, Decision Date: 06/10/2002, DZL (Class II per regulation 21CFR 872.4880)

6. Description of the Device

The LeForte Neuro system bone screw is made of Titanium alloy (ASTM F136) and consists of common bone screw, self-drilling screw (auto screw & NS auto screw). The common bone screws are classified to 4 classes: Micro screw, Mid screw, Mini screw, Maxi screw. And the auto screws (self-drilling screws) are divided to 3 classes; Micro auto, Mid auto, Mini auto screws. Additionally, the NS auto screws are divided to 2 classes. This device is manufactured and intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; selective orthognathic surgery of the maxilla and chin. Jeil Medical Corporation utilizes the state of the art technology and apply the essential requirements of MDD(93/42/EEC) and ISO 14630:1997 from the device design to manufacturing and QC.

7. Indications for Use (Intended Use)

This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; selective orthognathic surgery of the maxilla and chin.

8. Potential Adverse Affects and Complications (Common to all devices of this type)

1) Poor bone formulation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone, leading to nonunion.
2) Nonunion or delayed union which may lead to breakage of the implant.
3) Migration, bending, fracture or loosening of the implant.
4) Metal sensitivity, or allergic reaction to foreign body
5) Decrease in bone density due to stress shielding
6) Pain, discomfort, or abnormal sensation due to the presence of the device
7) Increased fibrous tissue response around the facture site and/or the implant
8) Necrosis of bone
9) Inadequate healing

Apart from these adverse effects there are always possible complications of any surgical procedure

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such as, but not limited to, infection, nerve damage and pain which may not be related to the implant.

9. Safety and Effectiveness, Comparison to Predicate Devices

Device Name	**Leforte Neuro System Bone Screw (New)**	**Synthes(USA) 1.3mm Craniofacial Screws (K021850)**	**Synthes(USA) Neuro Plate & Screw System (K042365)**
Applicant	Jeil Medical Corporation	Synthes(USA)	Synthes(USA)
Classification	Screw, Fixation, Intraosseous (Class II, 21 CFR 872. 4880)	Screw, Fixation, Intraosseous (Class II 21 CFR 872.4880)	Intraosseous fixation screw or wire (Class II, 21 CFR 872. 4880) Bone Plate (Class II, 21 CFR 872. 4760) Burr hole cover (Class II, 21 CFR 882. 5250)
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy
Intended Use	This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery: Reconstructive procedures; selective orthognathic surgery of the maxilla and chin;	This device is intended for use in selective trauma of the mid-face and craniofacial Skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	This device is intended for use in selective trauma of the mid-face and craniofacial Skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.
Single use	Single Use	Single Use	Single Use

Sterile	Non-sterile	Non-sterile	Non-sterile

10. Conclusion

In all respects, the Leforte Neuro System Bone Screws are the equivalent of currently marketed devices. They are made of the same materials and have similar dimensions and characteristics. Potential adverse effects are identical to those of the predicate devices. This device is manufactured from material of titanium alloy (ASTM F136) that is used generally in this kind of bone screw. Similar devices made from titanium alloy (ASTM F136) to this device are manufactured and sold around the world. This device, LeForte Neuro system bone screw is substantially equivalent in design, material, and function to the products on the table above. These devices are certificated by notified body for CE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Jeil Medical Corporation
C/O Mr. Shin Kuk Yoo
Manager
LSK BioPartners, Incoporated
215 South State Street, Suite 100B
Salt Lake City, Utah 84111

NOV 13 2009

Re: K091686
Trade/Device Name: LeForte Neuro System Bone Screw (Various Models)
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: October 19, 2009
Received: October 21, 2009

Dear Mr. Yoo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Exhibit 4 Indications for Use

510(k) number (if known): _____

Device Name: LeForte Neuro System Bone Screw (Various Models)

Indications for Use:

This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulay for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091686